Quality Assurance Program Plan

This Quality Assurance Program Plan provides an overview of the Laboratory's program to address the regulations contained in the most current revision of 10 *CFR* 830 Subpart A, *Quality Assurance.*

1.0   APPROVAL RECORD

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The official approval record for this document is maintained in the Training, Documents and Records Office, 151 TASF.

2.0   REVISION/REVIEW INFORMATION

The revision description for this document is available from and maintained by the author.

3.0   INTRODUCTION

This Quality Assurance Program (QAP) Plan describes how the quality assurance criteria of 10 CFR 830 Subpart A are addressed at the Ames Laboratory in order to provide reasonable assurance of adequate protection of workers, the public, and the environment from adverse consequences, taking into account the work to be performed and the associated hazards.

4.0   VOLUNTARY CONSENSUS STANDARDS

The development of this QAP plan is based on the criteria as defined in 10 CFR 830 Subpart A. Where necessary and applicable, the implementation of the QAP is supported by additional guidance as provided in DOE G 414.1-2B, and ANSI/ASQ Z 1.13-1999.

5.0   GRADED APPROACH

The graded approach concept refers to the process of ensuring that the level of analysis, documentation, and actions used to comply with a requirement are commensurate with characteristics related to an activity. This includes relative importance to safety, safeguards and security, magnitude of hazard involved, life cycle stage of a facility, programmatic mission of a facility, characteristics of a facility, and other relevant factors. Ames Laboratory does not apply requirements uniformly across all activities. Applying requirements uniformly would not necessarily add value or reduce risks and could be an ineffective allocation of resources.

The control and assessment mechanisms applied to safety processes and business functions at the Ames Laboratory are designed with the goal of providing effective and efficient assurance. A comprehensive account of the Ames Laboratory's assurance processes is provided by the Ames Laboratory Contractor Assurance System (CAS) Description.

6.0 PROGRAM INFORMATION – Quality Assurance Criteria

This QAP plan addresses management, performance and assessment criteria.

6.1 Criterion 1 – Program

6.1.1 10 CFR 830 Subpart A – Quality Assurance Requirements

(1) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.

(2) Establish management processes, including planning, scheduling, and providing resources for the work.

6.1.2 Program Information

The Ames Laboratory's organizational structure and management system are designed to accomplish the Laboratory's mission properly and safely. The organizational structure includes an Executive Council, led by the Laboratory Director, an oversight board, headed by the President of Iowa State University (the contractor), several independent offices, administrative and operations support departments, and research programs. Details about the Ames Laboratory, including its organizational structure, annual Laboratory Plan, and strategic plan are provided through its web pages. The Laboratory utilizes its management and organizational system, supplemented by formalized institutional planning, readiness review and budgeting processes to direct the planning, scheduling, resource allocation and performance of work at the Laboratory. The management system is also supplemented by documented requirements that establish clear and defined roles, responsibilities and authorities. Specific expectations of the Laboratory are communicated through U.S. D.O.E. Contract DE-AC02-07CH11358.

Roles and responsibilities of individuals are primarily documented through position descriptions as part of the hiring process, and additional definition of roles and responsibilities are provided through process documentation. Every employee is responsible for achieving quality performance in their activities. Annual performance evaluations are conducted to document individual performance.

6.2 Criterion 2 - Personnel Training and Qualification

6.2.1 10 CFR 830 Subpart A – Quality Assurance Requirements

(1) Train and qualify personnel to be capable of performing their assigned work.

(2) Provide continuing training to personnel to maintain their job proficiency.

6.2.2 Program Information

The Laboratory's hiring process ensures that personnel are qualified to carry out their assigned duties. Qualifications for each job position are documented in a job description and further detail is listed in the position description. Candidates are required to furnish information on their education, professional experience and other credentials that demonstrate their ability to perform the required duties and responsibilities. A researcher's education, experience and scientific expertise assure quality research. Interviews are conducted to verify competency and a candidate is selected who best matches the skills needed for the position. In addition, graduate students contribute significantly to the research efforts at the Ames Laboratory. University academic

departments screen these individuals as part of the admission process. References are checked to confirm the selected candidate's competency.

Once hired, performance appraisals are conducted to ascertain if the employee would benefit from additional training to perform their current job activities. Training to improve the quality and safety of work is considered when reviewing the individuals' training profile during the performance appraisal process.

The Laboratory's training program provides employees with the training necessary for the safe and productive completion of their work responsibilities. A primary emphasis is placed on the fulfillment of environment, safety, and health (ES&H) training requirements. The foundation of the training program is the needs assessment process, which identifies training requirements and needs for Laboratory employees. Subject matter experts (SMEs) provide training from various disciplines. Course evaluations are also obtained to continually improve the training elements. Employee training participation in relation to mandatory job requirements is tracked through the Laboratory's web-based training management system (Cyber Train), and is taken into consideration during the annual performance evaluation process.

The training program focuses on the following core activities: needs assessment program; institutional training courses; course development; job (activity) specific training; and training records management. The training program is detailed in the Training Program Manual (Manual 48202.001) and the Training Needs Assessment Process (Procedure 10200.029).

6.3   Criterion 3 - Quality Improvement

6.3.1   10 CFR 830 Subpart A – Quality Assurance Requirements

(1) Establish and implement processes to detect and prevent quality problems.

(2) Identify, control, and correct items, services, and processes that do not meet established requirements.

(3) Identify the causes of problems and work to prevent recurrence as a part of correcting the problem.

(4) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.

6.3.2   Program Information

The Laboratory has instituted continuous improvement programs as a result of the implementation of the Quality Assurance Order 414.1D. Areas strengthened include management planning, training, design, procurement, inspection & acceptance testing, documents and records, and assessments. The Laboratory continues to enhance its processes to support the principle of continuous improvement.

Continuous Improvement within the Scientific Process

The steps to ensure the continuous improvement of research in a diverse research environment include selecting highly qualified and motivated people to carry out the research, ensuring proper conduct of research, and obtaining reviews of results by independent, competent peers. The primary mechanisms for assuring quality in research are discussed below.

Conduct of Research

The primary responsibility for the proper conduct of the research lies with the principal investigator and their division or program director. They are responsible for planning and preparing research proposals. Proposals include a discussion of the research to be conducted, provide background information and research significance, and describe the research methodology, resource requirements, scheduling milestones, funding needs, and management plans. In addition, researchers utilize several quality assurance mechanisms during this planning and preparation phase of the research. First, all principal investigators on a proposal are critically knowledgeable of their particular research area. Second, the researcher will always perform an extensive literature search to keep abreast of what is known about a particular subject and what continues to be debated. Finally, a researcher may also decide to perform preliminary exploratory experiments to test a novel hypothesis prior to preparing the research proposal and performing a formal investigation.

Peer Review

The quality of research is assessed by the peer review process and by oversight from the sponsoring organization. Presenting research results at scientific and engineering conferences and meetings, as well as collaborating on a continuous basis with peers internally and externally to the Ames Laboratory provides necessary opportunities for feedback on research results from other individuals within the technical discipline being discussed. In addition, a program review process is in place for most of the scientific programs. Generally, a group of external reviewers is selected by the sponsoring agency to conduct the review. Reviewers present their findings, both verbally and in writing, to Laboratory management. The nature of the input includes an evaluation of the scientific and technical merit of the project, correctness of the scientific approach, competency of the personnel and adequacy of the proposed resources, and relevance to the mission of the institution. An additional part of the review is the subject of new directions in which the Ames Laboratory should extend its efforts to maintain a balanced program.

Continuous Improvement for Laboratory Operations

The Laboratory's continuous improvement activities provide support for business and safety programs.

Process Improvement Tools

Many tools for managing process improvement efforts are available, including process maps, gap analysis, formal implementation plans and application of software systems. These are common business practices for managing changes to requirements, and although they are not part of the recognized skill set of every employee, the Laboratory has individuals on staff with the experience necessary to provide guidance to employees undertaking process improvement efforts.

Employee Safety and Security Concerns Program

The Ames Laboratory safety and security concerns program is designed to encourage comments, opinions, and recommendations for the continuous improvement of Ames Laboratory work practices. Employee concerns are tracked and trended each year.

Lessons Learned

Internal and external lessons learned are distributed to all of the Ames Laboratory employees via the Laboratory's web page. Group/activity specific lessons learned are distributed when appropriate.

Safety Coordinator/Representative Program
Safety coordinators and safety representatives facilitate safety implementation in their respective organizations as directed by their group leaders, division directors, program directors or department managers.

Readiness Review Process
All new or significantly modified activities undergo a readiness review which identifies the hazards associated with the activity and establishes hazard management controls. Further information on this process is presented in section 6.5.

Assessment Program
The Laboratory assessment program consists of worker observations, walk-throughs, and external assessments. All observations that result from these assessments are tracked, closed-out, and verified in accordance with their assigned finding level. Further information on these assessment elements is presented in Sections 6.9 and 6.10.

6.4 Criterion 4 - Documents and Records

6.4.1 10 CFR 830 Subpart A – Quality Assurance Requirements

(1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.

(2) Specify, prepare, review, approve, and maintain records.

6.4.2 Program Information

The documents and records processes provide for the creation, maintenance and use, and final disposition of all Laboratory records. The "creation" phase addresses the importance of effective document control processes. The Document Control (DC) Program Plan ensures that only approved, current versions of such documents are used in the workplace or transmitted to outside entities. The "maintenance and use" phase requires that all inactive records are removed from high-cost office storage space and are indexed for easy retrieval. A successful program is founded on knowing what information is available and where it is located. Once records are electronically indexed, decisions can be made regarding the series disposition date, informational value, and how they can be managed until their final disposition. In the final phase, "disposition," records shall be secured and protected until they can be cleared for final destruction.

The documents and records core activities include document control; the maintenance, storing, and protecting of inactive records; and a sound vital records program. Document control is detailed in the Document Control Program Plan (Plan 10200.038), and the handling of vital records is described in the Vital Records Plan (Plan 48202.001).

Maintenance, Storage, and Protection
Maintenance, storage, and protection of records are primarily accomplished by the use of a database (Versatile), an electronic content management system, and storage within the Laboratory's Records Holding Area (RHA) and Warehouse Records Storage (WRS). Active records are adequately protected on-site by the Laboratory's access security controls and fire protection program. Inactive records are stored in the RHA and WRS, which have been renovated to meet the requirements of 36 CFR 1234.10 (Facility Standards for Records). Records placed in the RHA and WRS are secured and access limited. All records of the Ames Laboratory are unclassified.

6.5 Criterion 5 - Work Processes

6.5.1 10 CFR 830 Subpart A – Quality Assurance Requirements

(1) Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means.

(2) Identify and control items to ensure their proper use.

(3) Maintain items to prevent their damage, loss, or deterioration.

(4) Calibrate and maintain equipment used for process monitoring or data collection.

6.5.2 Program Information

Ames Laboratory management identifies the space, activities, and personnel for which programs / departments have management responsibilities.

Readiness Review of Activities
The Ames Laboratory has developed a set of requirements, supported by procedures and assessed through independent review, to ensure that activities have achieved operational readiness. The level of independence of review and the rigor of application of the requirements for work processes are commensurate with the degree of risks associated with the activities. The Laboratory's readiness review process provides a solid foundation for quality assurance and integrated safety management.

Control of Items
Items are generally considered as devices, tools and equipment; but can include hardware, samples, software, data or quality impacting consumables, e.g., chemicals, etc. Items should be identified and controlled to ensure their proper usage. The responsibility to prevent the usage of incorrect and defective items is assigned to the organizational unit with ownership or custodianship of the items.

Maintenance and Protection of Items and Equipment
The planning and performance of the maintenance and protection of items and equipment is the responsibility of the organizational unit with ownership or custodianship of the items or equipment. Facility infrastructure system items and equipment are maintained and protected through processes supported by Laboratory-wide services.

Calibration of Equipment
The Ames Laboratory group leaders are charged with the responsibility of assuring that measuring and test equipment is of proper type, accuracy, and tolerance to accomplish the specified requirements. Items shall be calibrated and adjusted at specified periods to maintain accuracy within necessary limits and shall have known valid traceable relationships to nationally recognized standards or the documented procedure of an Ames Laboratory expert. The frequency of calibration shall be determined on the basis of the equipment's required accuracy, intended use, frequency of use, stability characteristics and how it influences the quality of an item's characteristics.

6.6 Criterion 6 – Design

6.6.1 10 CFR 830 Subpart A – Quality Assurance Requirements

(1) Design items and processes using sound engineering / scientific principles and

appropriate standards.

(2) Incorporate applicable requirements and design bases in design work and design changes.

(3) Identify and control design interfaces.

(4) Verify or validate the adequacy of design products using individuals or groups other than those who performed the work.

(5) Verify or validate work before approval and implementation of the design.

6.6.2 Program Information

The design activities of the Ames Laboratory are primarily the responsibility of the Facilities and Engineering Services (FES) and Information Systems departments. Facilities and Engineering Services engineers primarily perform design activities related to the Ames Laboratory's facilities and infrastructure, and to the design and fabrication of research equipment. Design engineers and specialists are qualified by their educational degrees and/or experience and receive on-going professional development training in their area of expertise as necessary.

The design activities include, design requirements, design standards, design verification, design approval and validation, documentation of design and design changes.

Design Requirements
The requester establishes a set of functional design requirements. Generally, these requirements are specified on a service order requisition (SOR). The SOR is utilized to control and document the planning and development of design and fabrication activities with the service departments. SORs with significant hazards are reviewed by safety specialists; they are also reviewed for any potential safety impact to the requestor and/or the service provider. If the SOR describes a major engineering project (i.e., those exceeding a particular cost threshold) requiring design, then a work order (WO) or job order (JO) is assigned. In addition, new or significantly modified activities require a formal readiness review. Smaller work requests may only need to be reviewed by the requestor. The review process is commensurate with the scope of the activity and helps to ensure that all safety aspects are addressed prior to performance of the task.

Design Standards
The designer utilizes the functional design requirements outlined in the SOR and builds upon this information. The qualified designer or drafter prepares a formal design utilizing national codes and standards. Under design control, the project engineer/designer assumes additional responsibilities including: generation of preliminary plans, specifications, initial cost estimates, and project description; assuring performance to specification of the final product; cost control on the work order/job order; timely procurement of all materials or parts; completion of the design; project scheduling, project status tracking, setup and delivery of the final product; and documentation/ generation of final as-built specification drawings.

Design Verification
The project engineer/designer is the staff member most knowledgeable about the particular project. The rigor of the project design review is commensurate with the complexity or hazards associated with the system. If the project requires a team review then the team includes all the disciplines needed to accurately evaluate the design package. Any projects that involve welding shall be reviewed by a qualified engineer to

determine if the nature of the work requires that the welding be performed as part of the certified welding program. The review either recommends approval of the design package or identifies issues to be resolved.

Design Approval and Validation

Final designs, field changes, and modifications shall be approved by the original design organization or a technically competent designee and shall be translated into specifications and drawings. Once the system is established in accordance with the approved design then the system is actually tested to ensure it conforms to all requester and design requirements.

Documentation of Design

A project file folder is created for each project requiring $2,000 or more of service work effort. Design and fabrication project correspondence, including copies of purchase orders for procured parts, are contained or referenced in the project file. In addition, upon completion of a project, a quality assurance statement is signed and included with each project folder to assure the proper routing of a project through design, fabrication, testing, and delivery. Design notes on any significant design and/or fabrication field changes, provides additional documentation in the project file folder.

Design Changes

The project engineer/designer controls design changes. Simple changes may only require authorization from the project engineer. However, significant changes shall require a justification in writing and an analysis shall be made to ensure that the modified design meets the new design requirements. The project engineer is responsible for documenting changes via notes in the project file folder for future incorporation as needed into the as-built specifications and drawings.

6.7 Criterion 7 – Procurement

6.7.1 10 CFR 830 Subpart A – Quality Assurance Requirements

(1) Procure items and services that meet established requirements and perform as specified.

(2) Evaluate and select prospective suppliers on the basis of specified criteria.

(3) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

6.7.2 Program Information

Procurement purchases materials, equipment, and services consistent with best business practices and applicable regulations to provide timely, cost effective, and quality goods and services to Ames Laboratory customers. Materials and equipment with a safety concern are routed to subject matter experts to specify the requirement for the inspection of records and materials along with a documented QA program.

The procurement processes core activities include fulfilling procurement requests, sourcing from qualified suppliers, subcontracting, ensuring completed signature approval process, a quality assurance inspection system, and receipt inspection.

Procurement Requests

Procurement activities shall be planned and documented to assure a systematic approach to the procurement process. Requestors prepare purchase requisitions that include suitable specifications, standards, and/or purchase descriptions that clearly and accurately describe the items that are being requested. Buyers assist in the preparation of specifications when assistance is needed. The purchase requisition shall contain a justification for the purchase of the item or service and shall contain a valid project number to cover the associated costs. The Purchasing Office communicates with the requestor should there need to be any clarifications made before, during or after the purchase. Employees may be issued a government credit card to make purchases under the micro-purchase threshold; however, they must complete the appropriate on-line DOE Credit Card Training and an internal Ames Laboratory credit card training prior to activating their card. Cardholders reconcile their monthly statements in the Ames Lab database. The Purchasing Office conducts random reviews of credit card transactions each month. Facilities and Engineering Services reviews all credit card transactions to ensure the reliability and safety of the items purchased, Accounting reviews for allowability of purchases, and Property Services reviews items purchased to appropriately identify accountable personal property assets.

Sourcing / Qualified Suppliers and Subcontractors

The Purchasing Office identifies capable and reliable vendors / subcontractors who provide the best value to the Ames Laboratory. Awarding a subcontract based on lowest price can be false economy is subsequent default, late delivery, or other unsatisfactory performance results in added costs. Buyers will review the total cost of acquisition and award based on best overall value.

Representations and certifications are collected from each active supplier and all new suppliers. Sources are found via the Internet, identified through strategic sourcing agreements and through previous purchases. The Purchasing Office tabulates requestor feedback, tracks on-time delivery and assists with resolving any associated quality issues with purchases.

Signature Approval Process

Requisitions will not be processed by the Purchasing Office if the purchase requisition is missing any of the required approvals. Refer to the Ames Laboratory Accounts Authorization Handbook for more information.

Quality Assurance Inspection System

The quality assurance inspection system is a process where purchased items with a higher associated risk are reviewed by a technical expert. The expert ensures that the goods meet the required specifications of the Laboratory and the requestor. To implement this process, the Laboratory's Purchasing Office codes all purchased items by commodity and forwards higher risk purchases on to Facilities and Engineering Services for review to ensure that safety issues are addressed. Coded items not reviewed by Facilities and Engineering Services (except those exempted in section 6.72, see "signature approval process") are reviewed by the requestor and must meet their established acceptance criteria. Suspect and Counterfeit Items are also reviewed utilizing this system.

The Procurement Quality Procedure (46200.003) assures that only correct and accepted items are used or installed. The procedure directs the quality procurement review and inspection activities performed within the Ames Laboratory to review procured items for

quality and safety concerns. It provides instructions for the identification and control of materials, parts, components, and partially fabricated assemblies during fabrication, installation, maintenance or modification. Procurement works in conjunction with Ames Laboratory's Facilities and Engineering Services department regarding ordered materials; however, the main responsibility of this function is vested with the FES due to its technical nature. FES also provides training on the Procurement Quality Procedure for employees of Facilities and Engineering Services, and the Procurement Office. Technical training on the specific electronic and mechanical review and inspection activities is conducted with the FES-Electronics and FES-Mechanical Sections.

Receipt Inspection
Warehouse personnel are charged with the responsibility of receiving, inspecting, temporarily warehousing, tagging assets and delivering to the end user all incoming materials and equipment. When special inspection is required, support services from Facilities and Engineering Services are used to determine whether the received materials or equipment are in accordance with the subcontract. Procurement for services is verified by the requestor after the service has been rendered.

6.8   Criterion 8 - Inspection and Acceptance Testing

6.8.1   10 CFR 830 Subpart A – Quality Assurance Requirements

(1) Inspect and test specified items, services, and processes using established acceptance and performance criteria.

(2) Calibrate and maintain equipment used for inspections and tests.

6.8.2   Program Information

Inspection and acceptance testing of specified items is conducted utilizing established procedures. The inspection process involves the real-time quality control examination and/or observation of activities or items in relation to approved acceptance criteria as demonstrated by procedures, specifications, checklists or drawings. Items found to be nonconforming are discarded, reworked, returned to the vendor, or otherwise controlled by segregation or tagging to prevent their inadvertent use.

The main inspection and acceptance testing areas are procured items, measuring and test equipment, welding, hoisting and rigging equipment, and safety equipment.

Procured Items
A purchase requisition must be completed for every order that is processed through the Ames Laboratory Purchasing Office. The buyer will place the order and will work with the requestor to ensure that the vendor is offering items that conform to the specifications required. Purchase orders are coded to trigger a review by a Facilities and Engineering Services specialist if it meets certain criteria. Based upon the review it is determined if the purchase requires a formal inspection by a specialist or by FES. Once the item is received at the Ames Laboratory warehouse it is visually inspected for damage, matched against the purchase order and packing slip. The item is then routed to the requestor's specified delivery address by local transportation means. The requestor then inspects the goods for conformance with his/her specified requirements.

Calibration of Equipment
Inspection and testing is performed utilizing calibrated materials and testing equipment. The Ames Laboratory groups and departments are charged with the responsibility of

assuring that measuring and test equipment is of proper type, accuracy, and tolerance to accomplish the specified requirements. Items shall be calibrated and adjusted at specified periods to maintain accuracy within necessary limits and shall have known valid traceable relationships to nationally recognized standards or the documented procedure of an Ames Laboratory expert. The frequency of calibration shall be directly dependent upon the equipment's required accuracy, intended use, frequency of use, stability characteristics and how it influences the quality of an item's characteristics. Calibration verifications shall be documented and maintained by the appropriate group or department. Measuring and test equipment that is found out of calibration is identified and its impact is evaluated.

Welding

All welding (includes brazing and silver soldering, but does not include soft soldering nor spot welding for research purposes, e.g., thermocouples and electronic contacts) at the Ames Laboratory shall be performed by Facilities and Engineering Services.

Hoisting and Rigging

Hoists and cranes shall undergo inspection and load tests when installed and after major modifications or replacement of major load carrying parts. A technician with mechanical experience from Facilities and Engineering Services inspects hoists and cranes on an annual basis. A hoist and crane inspection label, which indicates the equipment's re-inspection date, shall be placed visibly on the equipment. The hoist or crane shall not be operated without a current inspection sticker in place.

All hoist and crane operators are required to attend the Laboratory's institutional training on Cranes, Hoisting and Rigging (AL-014). Participants review the current cranes, hoisting and rigging policy as outlined in the ESH&A Program Manual. In addition, a written training exercise is administered and the individual's program / department provides hands-on training. The verification of hoist and crane training is maintained via Cyber Train which also identifies the operator's five year re-train date.

Safety Equipment

Ames Laboratory personnel conduct inspections of various types of electrical tools related to safety. These inspections are based on criteria, such as the performance of the equipment and the performance of maintenance. The items are labeled to indicate physical inspection, test and/or the performance.

In-House Services

Ames Laboratory utilizes several in-house services departments, i.e., Facilities and Engineering Services (e.g., maintenance, sheet metal, carpentry, instrumentation and machine shops), and Information Systems, to provide items, equipment and services. All of these departments have a quality assurance form in place, which documents a requestor's satisfaction with the worked performed.

6.9 Criterion 9 - Management Assessment

6.9.1 10 CFR 830 Subpart A – Quality Assurance Requirements

Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.

6.9.2 Program Information

An important and effective process for identification and correction of deficiencies is the observation of individual employees. Worker observation guides are available to assist workers in the observation of activities within office spaces and laboratory / shop spaces. Work deficiencies should be corrected as soon as possible by the workers involved with the activity. Workplace deficiencies should be reported to the first level of management as soon as possible. Resolution of findings should occur at the level of line management most directly responsible for the activity. If the issue cannot be resolved at this level, the employee is directed to report the issue within his/her line management structure or to report the finding to the ESH&A office.

Supervisors and group leaders are accountable for oversight, direction, and guidance of work activities. Group leaders and supervisors should periodically review the work being conducted within their organization and correct any identified deficiencies. Formal documentation of this effort is not required, but unresolved findings should be presented to the appropriate program director / department manager or ESH&A.

Program directors / department managers assess the allocation of resources and the management of hazards associated with the activities of the groups within their organizations. Programs and departments conduct a walk-through approximately once per year. The Program / Department Walk-Throughs are documented and the issues addressed. Programs and departments shall report the distribution of walk-through findings by type to the ESH&A for trend analysis.

Additional approaches are used to accomplish introspective self-analysis as part of management assessment criteria. These include self-evaluation review activities within programs and divisions in preparation for DOE program reviews, the analysis conducted during development of PEMP (Performance Evaluation and Measurement Plan) input, the development and documentation of process improvements through process mapping and gap analysis, and the Internal Audit department's annual self-assessment. The performance and results of such self-analysis activities are reported through line management channels to the respective Executive Council representative and thereby are considered by the Laboratory Director in determination of the need for additional independent assessments.

6.10   Criterion 10 - Independent Assessment

6.10.1 10 CFR 830 Subpart A – Quality Assurance Requirements

(1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.

(2) Establish sufficient authority, and freedom from line management, for the group performing independent assessments.

(*3) Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.*

6.10.2 Program Information

The Laboratory conducts independent assessments to provide objective reviews of the work place and implementation status of programs.

Independent Walk-Throughs

Independent Walk-Throughs are conducted under the direction of the ESH&A office. A walk-through is performed on each program and department annually. The Independent Walk-Through team shall consist of representatives from upper management, ESH&A, Iowa State University, an Ames Site Office representative, the manager of Purchasing and Property Services, and appropriate safety specialists. ESH&A coordinates these walk-throughs and tracks corrective actions.

Topical Appraisals

ESH&A, Safeguards and Security (S&S), and other specialists perform topical appraisals as self and independent assessments. The topics include items related to effectiveness and efficiency of Quality Assurance and Contractor Assurance System (CAS) processes. The Laboratory, in agreement with the Ames Site Office, utilizes a graded approach to determine applicability and frequency of specific topical appraisals.

Internal Audit Function

The Internal Audit office conducts a broad, comprehensive program of internal auditing within the Laboratory. The Internal Audit function examines and evaluates the adequacy and effectiveness of the systems of management control provided by the Laboratory to direct its activities toward the accomplishment of its objectives in accordance with Laboratory policies and plans and the DOE prime contract. The Internal Audit office does not have authority or responsibility for the activities audited. The Internal Audit office allocates audit resources in accordance with the estimated level of inherent risks associated with Laboratory functions or activities. The Internal Audit Office submits reports to the Ames Laboratory Director, and tracks associated corrective actions. The contract provides for a direct reporting relationship to the Governing Board of the Contractor.

Director Designated Assessments

The Laboratory Director, in consultation with the Executive Council, annually performs an overview evaluation to determine whether the combination of planned Independent Assessments provides Laboratory management with sufficient assurance across all critical financial, business, operations, ES&H, security, and Quality Assurance and Contractor Assurance System (CAS) functions. Additional Independent assessments may be scheduled, based on this evaluation or other management concerns.